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FACSIMILE COVER SHEET

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DATE: September 2, 2008

TO: Examiner Kevin R. Kruer
Group Art Unit 1794

PHONE #: 571-272-1510
FAX #: 571-273-8300

Application No.: 10/790,338 OUR REF.: 2177.16US02
Applicant: Luthra et al.
Due Date: September 8, 2008

FROM: Curtis B. Herbert, Ph.D., Esq.
PHONE #: 612-605-1038

Attached is the following for filing in the above-identified application.

(1) Reply Brief.

Respectfully submitted,

Curtis B. Herbert, Ph.D., Esq.
Registration No. 45,443

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office, Fax No. 571-273-8300 on the date shown below.

September 2, 2008
Date

Curtis B. Herbert, Ph.D., Esq.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 2177.16US02

Luthra et al. Confirmation No.: 9411

Application No.: 10/790,338 Examiner: Kruer, K.

Filed: March 1, 2004 Group Art Unit: 1773

For: POLYMERIC NETWORK SYSTEM FOR MEDICAL DEVICES AND METHODS OF USE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES
REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF INTRODUCTORY COMMENTS

In response to the Examiner's Answer, Appellant provides comments regarding errors of law and fact with respect to the Examiner's Answer dated July 8, 2008. The remaining issues are discussed in detail in the Appellant's Brief. Pursuant to MPEP 1208, enclosed are (A) Identification page, (B) Status of claims (C) Grounds of rejection to be reviewed on appeal, and (D) Arguments.

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 50-3863.

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PATENT

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For: POLYMERIC NETWORK SYSTEM FOR MEDICAL DEVICES AND METHODS OF USE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

REPLY BRIEF FOR APPELLANT

STATUS OF CLAIMS

Claims 54-104, 151-197, 199-206, and 209-215 are pending, and all of the pending claims stand rejected. Claims 1-53, 105-150, 198, 207 and 208 have been canceled. All pending claims are being appealed.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. The rejection of claims 54-104, 151-197, 199-206, and 209-215 as unpatentable under 35 U.S.C. § 112, first paragraph, as being failing to comply with the written description requirement.

2. The rejection of claims 167, 170-189, and 206 as unpatentable under 35 U.S.C. § 112, first paragraph, as being failing to comply with the written description requirement.

3. The rejection of claims 54-104, 151-197, 199-206, and 209-215 as unpatentable under 35 U.S.C. § 112, second paragraph, as being indefinite.

ARGUMENTS

INTRODUCTORY COMMENTS

In response to the Examiner's Answer, Appellant provides comments regarding errors of law and fact with respect to the Examiner's Answer. The remaining issues are discussed in detail in the Appellant's Brief. The Examiner's Answer advances three sets of arguments, the first directed to the limitation "free of covalent crosslinks", the second directed to the limitation "26° C" and the third directed to the term "covalent" bonds. These arguments are addressed in the same order herein.

I. Regarding the Patent Office's written description rejection of the term "copolymer free of covalent crosslinks" in Groups 1 and 2 (claims 54-104, 151-169, 190-197, 199-206, and 209-215). Of these, claims 54, 151, and 190 are the independent claims.

A. Errors of Law

1. The Patent Office errs by requiring inherent support.

The Patent Office incorrectly uses an inherency standard to determine if the legal requirement for a written description is satisfied. For instance, the Patent Office states that the Applicant makes assumptions that "cannot rise to the level of inherency" and that inherency requires the property to be "necessarily present", see Examiner's Answer page 5, last paragraph. This error leads the Patent Office to mistakenly deny the claims on the grounds that it might be possible for the claimed polymers to be crosslinked in some circumstances.

But all that is required to satisfy the description requirement is that the originally filed disclosure would have conveyed to one having ordinary skill in the art that the Applicant had possession of the concept of what is later claimed. In this case, Applicant pointed to particular Examples wherein no crosslinking chemicals were used such that the resultant copolymers were free of covalent crosslinks. Applicant therefore possessed the concept of copolymers free of covalent crosslinks. It does not matter that it would be possible to add crosslinking agents to the Applicant's copolymers. It is clear error for the Patent Office to use the wrong legal standard.

2. The Patent Office errs by shifting the burden of proof to the Applicant to provide support for the claims in the absence of ipsis verbis support.

The Patent Office maintains that there is no explicit or inherent support for the limitation "free of covalent crosslinks" and denies that Applicant has provided a basis for implicit support for the claims. The Patent Office has denied the claims on the grounds that the Patent Office has carried its burden of proof and Applicant has failed to rebut its case.

Respectfully, this position is clear error and directly contradictory to established case law as explicitly stated in In re Wertheim, 541 F.2d 257, 191 U.S.P.Q. 90 (CCPA, 1976): "**The PTO has done nothing more than to argue lack of literal support, which is not enough.** If lack of literal support alone were enough to support a rejection under §112, then the statement of In re Lukach, supra, 442 F.2d at 969, 58 CCPA at 1235, 169 USPQ at 796, that 'the invention claimed does not have to be described in ipsis verbis in order to satisfy the description requirement of §112,' is empty verbiage. **The burden** of showing that the claimed invention is not described in the specification **rests on the PTO** in the first instance, and **it is up to the PTO to give reasons why a description not in ipsis verbis is insufficient**." In re Wertheim, 541 F.2d 257, 265, 191 U.S.P.Q., 90, 98 (emphases added).

In the instant case, the Patent Office is required to provide a clearly articulated rationale as to why the artisan will not understand that Applicant has possession of the claimed invention. The Patent Office has declined to do so and maintains that "since the term is not explicitly supported by the specification, a prima facie case is considered to be sufficiently established", Examiner's Reply, page 5, third paragraph. After incorrectly shifting the burden of proof to Applicant, the Patent Office attempts to rebut the Applicant's responses using an inherency standard, which is the wrong standard, as explained above.

B. Errors of Fact

1. The Patent Office errs by insisting that artisans do not understand that monomers make crosslinked polymers in the absence of crosslinking agents.

The Applicant's position is that an artisan understands that a monomer undergoing a polymerization process will normally form a linear polymer in the absence of a crosslinking

agent and maintains that this understanding is foundational to the polymer sciences. When the artisan reads the specification, for instance the cited Examples in the Application, it will be immediately understood that the polymers are not crosslinked because there are no crosslinking agents present. And when reading the specification, when crosslinking agents are not mentioned as being required, the artisan will understand that Applicant possessed the concept of not using crosslinking agents, i.e., making copolymers free of covalent crosslinks.

The Patent Office argues that monomers could be polymerized to make crosslinked polymers, for instance, if hydroxyls or other groups of the monomers were reacted, and points to U.S. 6,530,950 to Alvarado (Examiner's Reply, page 6, last paragraph) in support. The problem with the Patent Office's argument is that it is not relevant whether or not the polymers could be crosslinked: what is relevant is whether the Applicant possessed the concept of not crosslinking them as claimed. The Patent Office effectively admits that the concept of no-crosslinks was present by arguing that further chemical reactions might be used to react the hydroxyls or other functional groups, i.e., if a crosslinker were used.

The Patent Office errs by arguing that polymerized monomers will not normally form polymers free of crosslinks in the absence of a crosslinker. ("Appellant provides no evidence to support the conclusion that it is a 'foundational principle of polymer science' that such polymer will be free of crosslinks via the reaction of two monomers consisting of a single double bond to make a linear chain", examiner's Reply, page 6, last paragraph). It is well known that monomers make polymers in the absence of crosslinking agents and there is ample evidence of the same. For instance, Figures 1A-1D of U.S. 6,530,950 to Alvarado (of record) depict four different monomers. The double bonds depicted as CH_2=CH react with each other to form a linear polymer. There would normally have to be two such CH_2=CH double bonds or a crosslinker chemical that reacts the other groups of the monomers with each other in order for the polymers to be come crosslinked. This understanding is fundamental to polymer chemistry, for instance U.S. 6,530,950 to Alvarado at column 5 lines 27-38 explains that an acrylate monomer (Fig. 1A therein) makes an acrylic acid polymer of formula -(CH_2-CH(COOR))n- and that a methacrylate monomer (Fig. 1B therein) makes a polymer of methacrylic acid of formula -(CH_2-C(CH_3)(COOR))n- . These are formulas for not-crosslinked polymers.

The Patent Office points to U.S. 6,530,950 to Alvarado for the proposition that monomers can be used to make crosslinked materials. Such an action, however, requires a crosslinking agent, e.g., as in U.S. 6,530,950 to Alvarado that explicitly describes using crosslinkers, e.g., column 8 line 7 or column 8 line 23.

2. Applicant's figures and specification disclose not-crosslinked polymers; The Patent Office errs by proposing that the claims be limited to the Examples in the case that appellant prevails.

Applicant maintains that the limitation "free of covalent crosslinks" would be understood as being broadly disclosed and possessed by Applicant. For instance, there is written description support in the Figures, which depict copolymers that are not crosslinked covalently or otherwise: (a) Figure 1A depicts a copolymer free of covalent crosslinks. Copolymer (301) is made of monomers 300, 302 and are linear (not crosslinked). Monomers 300 have a Tg relatively lower than compared to monomers 302. Application page 6, lines 5-7. (b) Figures 1B-1C depict copolymers (301) free of covalent crosslinks, with low Tg domains (303) and high Tg domains (304). Application page 6, lines 17-18. The low Tg monomeric units 300 and high Tg monomeric units 302 tend to form domains 303, 304. Application page 6, lines 8-9. Polymeric blocks may form domains as a result of thermodynamic forces, e.g., ion-ion, or hydrophobic-hydrophilic forces. Application page 9, lines 11-20.

Accordingly, Applicant maintains that the limitation "free of covalent crosslinks" broadly supported beyond examples 1-5 such that it would be error to find that the claims are not commensurate with the claimed invention.

II. Regarding the Patent Office's written description rejection of the term "26 degrees Centigrade" in Groups 2 and 3 (claims 167, 170-189, and 206).

Claims 167, 170-189, and 206 are directed to a copolymer or coating with a glass transition temperature between 26 and about 40 degrees Centigrade.

A. Errors of law

1. No prima facie case for the written description rejection has been made.

The Patent Office has made a written description rejection based on a lack of ipsis verbis support for the 26 degree limitation. As per *In re Wertheim* quoted above, such a rationale is not

legally adequate ("it is up to the PTO to give reasons why a description not in *ipsis verbis* is insufficient"). No other rationale has been provided for this rejection despite Applicant's quotation of language in the specification at page 12 lines 15-19 that plainly and explicitly states that all ranges and values from about 0°C to about 40°C are contemplated. The Patent Office makes counter-arguments to other points raised by Applicant but these counter-arguments do not provide a rationale for the rejection.

2. The Applicant has the right to amend the claims to recite an endpoint within a range.

In re Wertheim directly addresses the present issue and is discussed at length in Appellant's brief at page 7-9, see In re Wertheim, 541 F.2d 257, 265, 191 U.S.P.Q. 90, 98 and 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97. Other relevant caselaw is also discussed in the brief at pages 7-9, including caselaw that states that Applicant does not need to demonstrate criticality of an endpoint of a range to meet a description requirement.

B. Errors of fact

1. The claimed limitation of 26 degrees is explicitly supported

The specification at page 12 lines 15-19 explicitly states that all ranges and values from about 0°C to about 40°C are contemplated. The Patent Office incorrectly rejects this statement as providing adequate support.

The Patent Office points out that a patient with a temperature of about 26 degrees Centigrade is almost assuredly dead such that Applicant's other arguments about this temperature being supported by disclosure that "temperatures approaching physiological temperatures" are unreasonable. The Application, however, discloses that Tgs may be quite low, e.g., -49°C or -23°C (page 8 lines 6-9 of Application) such that 26°C may be reasonably viewed as "approaching" physiological temperatures.

2. The claimed limitation of 26 degrees is implicitly supported

The Application at page 8 lines 6-9 discloses polymers with various Tgs, including -23°C (page 8 line 8). The Application at page 10 line 16 states that a suitable predetermined Tg difference may be about 50 degrees. The difference of about 50 degrees from -23°C is about 27°C, which provides implicit support for what is claimed, i.e., a copolymer glass transition of 26 degrees C.

III. Regarding the Patent Office's indefiniteness rejection of the term "covalent" crosslink in Groups 1, 2 and 3 (claims 54-104, 151-197, 199-206, and 209-215).

The Patent Office maintains that the ordinary artisan can not distinguish between a covalent crosslink and an ionic crosslink.

Applicant maintains that one with ordinary skill in the art would understand the scope of the term "covalent" as claimed for reasons already provided. Evidence defining these terms and their use as customary in these arts is of record.

CONCLUSIONS

Applicants believe that the Patent Office has failed to meet its burden of persuasion with respect to unpatentability of any of the claims on the present record. Thus, Applicant respectfully requests the Appeals Board to reverse of the rejections of the claims.

Respectfully submitted,

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